

IMI2 JU INDEPENDENT OBSERVERS' REPORT

Call ID: H2020-JTI-IMI2-2016-10-two-stage

IMI-2 10th Call for Proposals

Stage 2 Evaluation

Date of evaluation: 13 – 16 November 2017

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1. Introduction and approach taken by the observers

The present document is the report of the independent Observers on the assessment of Stage 2 of the 10th Call for proposals by the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) in Horizon 2020:

Call for Proposals: H2020-JTI-IMI2-2016-10-two-stage

Published: 21 December 2016

Deadline: 19 October 2017 – 17:00:00 Brussels time

Budget: from EFPIA companies and IMI2 Associated Partners: EUR 174 140 000
from IMI2 JU: EUR 173 890 000

This report contains the main findings of the independent Observers assessing the efficiency of the conduct of the procedures, usability of the System for the Evaluation of Proposals instrument, the conduct and fairness of the evaluation sessions, and the compliance with the applicable rules in particular application of the evaluation criteria by the evaluators.

For Stage 2 each of the first-ranked full proposals (8 out of 36) of the following topics was evaluated:

- Topic 1: Understanding hypoglycaemia: the underlying mechanisms and addressing clinical determinants as well as consequences for people with diabetes by combining databases from clinical trials
- Topic 2: How big data could support better diagnosis and treatment outcomes for prostate cancer (part of the Big Data for Better Outcomes programme)
- Topic 3: Improving the care of patients suffering from acute or chronic pain (this topic includes three subtopics on patient reported outcomes; biomarkers; and chronic pelvic pain)
- Topic 4: Creation of a pan-European paediatric clinical trials network
- Topic 5: Biomanufacturing 2020: development of innovative high throughput analytical tools and methods to characterize cell culture fluid during development and commercial cell culture processes
- Topic 6: Unlocking the solute carrier gene-family for effective new therapies (unlock SLCs)
- Topic 7: Patient perspectives in medicines lifecycle
- Topic 8: Personalised medicine approaches in autism spectrum disorders

For each topic 5 to 9 independent experts participated to the remote evaluation and to the panel meeting.

All relevant information was made available to the Observers in different forms: email with relevant links, a set of key documents linked together in a paper document was provided, a set of documents including CVs of experts on a USB key handed out at the beginning of the meetings. This was timely and useful information to the Observers.

The Observers monitored the evaluation process at the same time as the experts and had the chance to discuss with the majority of them.

The Observers attended to all general presentations delivered by the IMI2 JU Executive Director to the Panel members on the morning of each of the Panel group meetings. This was very useful for all experts and Observers as they got a brief, comprehensive overview of the IMI2 JU context, content and evaluation sequence. During the Panel group meetings, the role of the Observers was clearly defined and both Observers were presented to the experts.

Submitted full proposals were remotely evaluated by Independent Experts (IEs) and Observers had access to both full proposals and all expert reports.

Moderators for all Topic Panels gave a specific short briefing before panel discussions.

A complete day has been dedicated to each full proposal, two proposals evaluated in parallel on each day. The morning agenda was devoted to a general briefing followed by an introduction by the moderator to explain the second stage evaluation process including the hearing process and then a discussion to prepare the questions for the hearing. The afternoon started by the hearing, followed by the finalisation of the Consensus Evaluation Report to provide the applicants with fair/clear feedback.

In execution of their task the Observers took the following approach:

- Reading all specific IMI2 JU documents, especially the Annual Work Plan 2016 including the 8 Topics of the 10th Call (H2020-JTI-IMI2-2016-10-two-stage) and relevant rules and guidelines.
- Examining aggregated comments of the remote individual evaluation reports of the experts, Questions raised for the hearing, Consensus Evaluation Reports and Panel reports.
- Attending the panel meetings throughout each session for the 8 topics including hearing. Each of the Observers covered 4 topics.
- Having informal discussions throughout the evaluation process, with various IMI2 JU staff members, including lawyers, Head of Scientific Operations and Executive Director, experts and rapporteurs.
- Debriefing each other and exchanging impressions and observations in between meetings and global debriefing each end of day.

2. Overall impression

- None of the independent Observers observed any apparent violations of the published rules, procedures and guidelines, which were timely published and transparent.
- The Observers wish to underline that the experts have shown a high degree of motivation and interest, honesty and fairness in their evaluation work, dedication and integrity.
- The prevention and management of conflicts of interest was well undertaken by IMI scientific and legal officers and no case of conflict of interest was observed.
- The diversity and the proportion of experts with industrial, regulatory, academic etc. expertise was also very good, leading to very fruitful discussions. The experts had the relevant expertise for the evaluation of each topic.
- There was full agreement among the experts on given marks for each criterion. The Consensus Evaluation Reports were drafted with active participation of all Panel members, reviewed and agreed collectively, under the guidance of the IMI2 JU scientific and legal officers, ensuring the comments and recommendations were aligned with the scores.
- The role of the moderators (IMI2 JU Scientific Officers) was very important in guiding the discussion and providing clarifications, while not affecting the outcome.

3. Any other remarks

The Observers have the following other remarks:

- The quality of the documentation provided to experts beforehand was satisfactory.
- The allocation of experts to proposals was diverse; geographic and gender balance were good and expertise well covered.
- The process of the individual evaluations and the actors involved was excellent; the process of the consensus meetings including hearings and the actors involved was rigorous and responsible.
- According to experts workload and time given for their work, remotely and/or on-site, was sufficient.
- Overall conduct of staff, responsiveness, hospitality, competence, was very good.
- The infrastructure and working conditions for evaluators were good.
- The evaluation was conducted by the IMI2 JU staff in a very professional way.
- The evaluation involved important logistics preparation of the meetings (travels, hotel booking, printing evaluation reports, call documents, applicant proposals, IT system etc.). None of the experts expressed a complaint.

4. Summary of Recommendations

- There were no apparent violations of the published Guidelines and the evaluations, and discussions were fair and transparent.
- All evaluation IMI2 JU procedures have been fully respected.
- The well-defined evaluation procedures, the high scientific level of Independent Experts and the skilled Scientific Officers supported by a very competent staff allowed the proposals to benefit of an outstanding quality assessment.
- All participants approached their tasks with commitment and professionalism. As for Stage 2 the final assessment represents a go/no go decision, the discussion between the experts was sometimes quite hard but each time a real consensus decision was taken.
- The Consensus Evaluation Reports were drafted with active participation of all Panel members and the rapporteur under the guidance of the IMI2 JU Scientific Officers. The scores and the comments faithfully represent the consensus opinion of the Panels. Evaluation of the proposals, panel discussions and questioning of the applicants, were open-minded and impartial.

It should be emphasized that the IMI2 JU assessment procedures have reached a very high level of quality directly connected to the expertise, professionalism and competence of its employees.

The following sections collate comments we received from participants over all days of the meeting and give some recommendations and suggestions for modifications that could further improve the process for future Calls:

- Although the rationale for their intervention was understood, some experts found that the content of the Consensus Evaluation Reports risked to be altered by the review of the lawyers. It is recommended that lawyers pay particular attention not to change the scientific meaning of the message the experts wish to convey to the proponents.
- As experts are not allowed to make recommendations in the consensus report but only describe shortcomings, some experts found that their scientific role was weakened and recommended the permit of recommendations be made to improve the monitoring of the granted proposal.
- Some experts suggest that their individual report should be sent to the applicants as they are scientifically more informative than the consensus report and can help in the implementation of the project.
- Some experts suggested that the rapporteur should receive the aggregated reviews earlier to be able to prepare in advance a first draft of the consensus report. This will speed up the final consensus report drafting.
- Some experts expressed frustration at having only one full proposal at Stage 2 (in particular when the second ranked proposal had also been considered excellent at the first stage), as lack of competition does not ensure that the quality of full proposal is as high as it could be. (even when the level of partners was indisputable); they recommended a second proposal to be accepted at Stage 2 in exceptional, well justified cases.

5. Acknowledgements

Our thanks to the experts for agreeing to be “observed” and for the conversations that helped us formulate this report.

We particularly thank the IMI staff for their help, competence and hospitality before, during and after our stay in Brussels.